

CLAIMS

We claim:

- 1 1. A method for predicting the risk of a disease, comprising the steps of:
 - 2 a) providing a saliva sample from a subject;
 - 3 b) isolating a mucin in said saliva sample to produce an isolated
4 mucin; and
 - 5 c) quantitating the content of a component of said isolated mucin to
6 predict the risk of a disease in said subject.
- 1 2. The method of Claim 1, wherein said saliva sample is a stimulated saliva
2 sample.
- 1 3. The method of Claim 1, wherein said saliva sample is an unstimulated
2 saliva sample.
- 1 4. The method of Claim 1, wherein said component is total apomucin.
- 1 5. The method of Claim 1, wherein said component is total carbohydrate.
- 1 6. The method of Claim 1, wherein said component is sialic acid.
- 1 7. The method of Claim 1, wherein said mucin is MUC7 mucin.
- 1 8. The method of Claim 1, wherein said mucin is MUC5AC mucin.
- 1 9. The method of Claim 1, wherein said mucin is MUC5B mucin.
- 1 10. The method of Claim 1, further comprising the step of reporting the
2 content of said component in said isolated mucin as units per milliliter of said
3 saliva sample.
- 1 11. The method of Claim 1, further comprising the step of assessing the risk
2 of said disease as high, medium or low.
- 1 12. The method of Claim 1, further comprising the step of assessing the risk of
2 future development of said disease in said subject.

1 13. The method of Claim 12, further comprising the step of assessing the risk
2 of future development of said disease in said subject at subsequent ages.

1 14. The method of Claim 1, wherein said isolating step comprises isolating
2 said mucin using SDS-PAGE.

1 15. The method of Claim 1, wherein said quantitating step comprises
2 specifically binding said component in said isolated mucin.

1 16. The method of Claim 15, wherein said binding comprises direct binding or
2 facilitated binding.

1 17. The method of Claim 16, wherein said direct binding comprises dye-
2 binding.

1 18. The method of Claim 16, wherein said facilitated binding comprises
2 linking a specifically binding member pair to a surface that specifically binds to
3 said component of said isolated mucin.

1 19. The method of Claim 18, wherein said specifically binding member pair is
2 selected from the group consisting of antibodies and lectins.

1 20. The method of Claim 1, wherein said subject is a human.

1 21. The method of Claim 20, wherein said human is selected from the group
2 consisting of males and females.

1 22. The method of Claim 20, wherein said subject is aged between 18 and 35
2 years old.

1 23. The method of Claim 1, wherein said disease is selected from the group
2 consisting of dental caries, periodontal diseases, pulmonary diseases, respiratory
3 diseases, cardiovascular diseases, diabetes, perinatal disorders, mucosal
4 infections, oral cancers, pharyngeal cancers, precancerous lesions, associated
5 autoimmune disorders, HIV, osteoporosis, and a combination thereof.

- 1 **24.** The method of Claim 23, wherein said periodontal diseases are selected
2 from the group consisting of gingivitis, adult periodontitis, early-onset
3 periodontitis, and a combination thereof.
- 1 **25.** The method of Claim 23, wherein said cardiovascular diseases are selected
2 from the group consisting of heart attack, stroke and atherosclerosis.
- 1 **26.** The method of Claim 23, wherein said perinatal disorders are selected
2 from the group consisting of low birth weight and preterm births.
- 1 **27.** The method of Claim 23, wherein said diabetes is Type 1 diabetes or Type
2 2 diabetes.
- 1 **28.** The method of Claim 23, wherein said mucosal infections are selected
2 from the group consisting of oral candidiasis, herpes simplex virus infections,
3 herpes zoster virus infections, varicella zoster virus infections, human
4 papillomavirus infections, oral human papillomavirus infections, recurrent
5 aphthous ulcers, and combinations thereof.
- 1 **29.** The method of Claim 28, wherein said herpes simplex virus is Type 1 or
2 Type 2.
- 1 **30.** The method of Claim 23, wherein said disease is dental caries.
- 1 **31.** The method of Claim 30, wherein said dental caries is selected from the
2 group consisting of early-onset dental caries, adult dental caries, root caries, DFT,
3 DMF, and DMFS.
- 1 **32.** A method for reducing the risk of a disease, comprising the steps of:
2 a) providing a saliva sample from a subject;
3 b) isolating a mucin in said saliva sample to produce an isolated
4 mucin;
5 c) quantitating the content of a component in said isolated mucin; and
6 d) administering a therapeutic reagent to said subject when the

7 content of said component in said isolated mucin significantly falls below the
8 level expressed in an oral fluid standard.

1 33. The method of Claim 32, wherein said saliva sample is a stimulated saliva
2 sample.

1 34. The method of Claim 32, wherein said saliva sample is an unstimulated
2 saliva sample.

1 35. The method of Claim 32, wherein said component is total apomucin.

1 36. The method of Claim 32, wherein said component is total carbohydrate.

1 37. The method of Claim 32, wherein said component is sialic acid.

1 38. The method of Claim 32, wherein said mucin is MUC7 mucin.

1 39. The method of Claim 32, wherein said mucin is MUC5AC mucin.

1 40. The method of Claim 32, wherein said mucin is MUC5B mucin.

1 41. The method of Claim 32, wherein said isolating step comprises isolating
2 said mucin using SDS-PAGE.

1 42. The method of Claim 32, wherein said quantitating step comprises
2 specifically binding said component of said isolated mucin.

1 43. The method of Claim 42, wherein said binding comprises direct binding or
2 facilitated binding.

1 44. The method of Claim 43, wherein said direct binding comprises dye-
2 binding.

1 45. The method of Claim 43, wherein said facilitated binding comprises
2 linking a specifically binding member pair to a surface that specifically binds to
3 said component of said isolated mucin.

1 **46.** The method of Claim 45, wherein said specifically binding member pair is
2 selected from the group consisting of antibodies and lectins.

1 **47.** The method of Claim 32, wherein said subject is a human.

1 **48.** The method of Claim 47, wherein said human is selected from the group
2 consisting of males and females.

1 **49.** The method of Claim 32, wherein said subject is aged from between 18 to
2 35 years of age.

1 **50.** The method of Claim 32, wherein said disease is selected from the group
2 consisting of periodontal diseases, pulmonary diseases, respiratory diseases,
3 cardiovascular diseases, diabetes, perinatal disorders, mucosal infections, oral
4 cancers, pharyngeal cancers, precancerous lesions, associated autoimmune
5 disorders, HIV, osteoporosis, and a combination thereof.

1 **51.** The method of Claim 50, wherein said periodontal diseases are selected
2 from the group consisting of gingivitis, adult periodontitis, early-onset
3 periodontitis, and a combination thereof.

1 **52.** The method of Claim 50, wherein said cardiovascular diseases are selected
2 from the group consisting of heart attack, stroke and atherosclerosis.

1 **53.** The method of Claim 50, wherein said perinatal disorders are selected
2 from the group consisting of low birth weight and preterm births.

1 **54.** The method of Claim 50, wherein said diabetes is Type 1 diabetes or Type
2 2 diabetes.

1 **55.** The method of Claim 50, wherein said mucosal infections are selected
2 from the group consisting of oral candidiasis, herpes simplex virus infections,
3 herpes zoster virus infections, varicella zoster virus infections, human
4 papillomavirus infections, oral human papillomavirus infections, recurrent
5 aphthous ulcers, and combinations thereof.

1 **56.** The method of Claim 55, wherein said herpes simplex virus is Type 1 or
2 Type 2.

1 **57.** The method of Claim 32, wherein said disease is dental caries.

1 **58.** The method of Claim 57, wherein said dental caries is selected from the
2 group consisting of early-onset dental caries, adult dental caries, root caries, DFT,
3 DMF, and DMFS.

1 **59.** The method of Claim 57, wherein said therapeutic reagent is an anti-caries
2 reagent.

1 **60.** The method of Claim 32, wherein said oral fluid standard comprises a
2 sample from a normal control.

1 **61.** A diagnostic kit for detecting a disease comprising:

- 2 a) a means for collecting a saliva sample;
3 b) a means for isolating a mucin in said saliva sample, to produce an
4 isolated mucin;
5 c) a means for measuring the amount of a component in said isolated
6 mucin; and
7 d) an oral fluid standard for comparing the amount of said component
8 in said isolated mucin.

1 **62.** The method of Claim 61, wherein said oral fluid standard comprises the
2 content of said component in said mucin of a normal subject.

1 **63.** The diagnostic kit of Claim 61, wherein said disease is selected from the
2 group consisting of dental caries, periodontal diseases, pulmonary diseases,
3 respiratory diseases, cardiovascular diseases, diabetes, perinatal disorders,
4 mucosal infections, oral cancers, pharyngeal cancers, precancerous lesions,
5 associated autoimmune disorders, HIV, osteoporosis, and a combination thereof.

1 **64.** The diagnostic kit of Claim 63, wherein said periodontal diseases are
2 selected from the group consisting of gingivitis, adult periodontitis, early-onset
3 periodontitis, and a combination thereof.

1 **65.** The diagnostic kit of Claim 63, wherein said cardiovascular diseases are
2 selected from the group consisting of heart attack, stroke and atherosclerosis.

1 **66.** The diagnostic kit of Claim 63, wherein said perinatal disorders are
2 selected from the group consisting of low birth weight and preterm births.

1 **67.** The diagnostic kit of Claim 63, wherein said diabetes is Type 1 diabetes or
2 Type 2 diabetes.

1 **68.** The diagnostic kit of Claim 63, wherein said mucosal infections are
2 selected from the group consisting of oral candidiasis, herpes simplex virus
3 infections, herpes zoster virus infections, varicella zoster virus infections, human
4 papillomavirus infections, oral human papillomavirus infections, recurrent
5 aphthous ulcers, and combinations thereof.

1 **69.** The diagnostic kit of Claim 68, wherein said herpes simplex virus is Type
2 1 or Type 2.

1 **70.** The diagnostic kit of Claim 63, wherein said disease is dental caries.

1 **71.** The diagnostic kit of Claim 69, wherein said dental caries is selected from
2 the group consisting of early-onset dental caries, adult dental caries, root caries,
3 DFT, DMF, and DMFS.